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|---------------------------------|-------------|----------------------|-----------------------|------------------|
| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
| 10/548,748                      | 09/08/2005  | Markus Frank         | 12810-00137-US        | 1250             |
| 23416                           | 7590        | 12/10/2008           | EXAMINER              |                  |
| CONNOLLY BOVE LODGE & HUTZ, LLP |             |                      | IBRAHIM, MEDINA AHMED |                  |
| P O BOX 2207                    |             |                      | ART UNIT              | PAPER NUMBER     |
| WILMINGTON, DE 19899            |             |                      | 1638                  |                  |
| MAIL DATE                       |             | DELIVERY MODE        |                       |                  |
| 12/10/2008                      |             | PAPER                |                       |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                     |
|------------------------------|-------------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>        | <b>Applicant(s)</b> |
|                              | 10/548,748                    | FRANK ET AL.        |
|                              | Examiner<br>Medina A. Ibrahim | Art Unit<br>1638    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 07 August 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-3,6-17,19,20,23 and 25-27 is/are pending in the application.
  - 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 6-11, 14-17, 19-20, 23, and 25-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Applicant's response filed 08/07/08 in reply to the Office action of 02/07/08 has been entered. Claims 1, 14 and 25 are amended. Claims 22 and 24 cancelled. New claims 26-27 are added. Therefore, claims 1-3, 6-17, 19-20, 23, and 25-27 are pending.

This application contains claims 12-13, drawn to an invention nonelected with traverse in the reply filed on 03/16/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144)

See MPEP § 821.01.

2. Claims 1-3, 6-11, 14-17, 19-20, 23, and 25-27 are examined.  
3. All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims and/or upon further consideration.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 6-11, 14-17, 19-20, and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating a plant to at least one plant pathogen by transforming the plant with an isolated nucleic acid encoding the unmodified Bax 1 protein of SEQ ID NO: 2 under the control of a desired promoter, and a recombinant vector/cassette comprising said nucleic acid, does not reasonably provide enablement for a method that employs exemplified or non-exemplified nucleic acid sequences to increase resistance to all biotic and abiotic stresses in a transgenic plant or a recombinant vector/cassette comprising said nucleic

acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 02/07/08. Applicant's arguments filed 08/07/08 have been fully considered but all are not deemed persuasive.

Applicant's asserts that the amendment to the claims to recite at least 90% to SEQ ID NO: 2 would obviate the rejection. This is not found persuasive, however, because Applicant provides no evidence that shows the resistance to biotic and all abiotic stresses can be improved using exemplified or non-exemplified nucleic acid sequences. The instant specification discloses transgenic plants expressing BI1 sequences and having resistance to various plant pathogens. Applicant has not disclosed a single transgenic plant having resistance to heat, cold, drought, increased humidity, UV radiation or chemical stresses as a result of expressing exemplified or non-exemplified BI1 sequences. Therefore, given the lack of guidance in the specification and in the prior art; the unpredictability inherent in transforming plants for universal disease resistance as evidenced by Ryals et al (1996) and Mittler et al (1996); state of the prior art, and the limited working examples as discussed above and in the last Office action, the claimed invention cannot be practiced throughout the broad scope without undue experimentation. Therefore, the rejection is proper.

***Claim Rejections - 35 USC § 103***

Claims 1-3, 6-11, 14-17, 19-20, 23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons et al (WO 2002101079A2, Applicant's IDS) in view of Huckelhoven et al (Plant Mol. Biol. (2001) 47 (6):739-748). This rejection is repeated for the reasons of record as set forth in the last Office action of 02/07/08. Applicant's arguments filed 08/07/08 have been fully considered but all are not deemed persuasive.

Applicant argues that neither Simmons nor Huckelhoven teaches or suggests the expression of BI1 genes is essentially unchanged or reduced in leaf epidermis or teaches the use of a tuber or a mesophyll-specific promoter with the BI1 gene; therefore the claimed invention is not obvious over the cited references (response, pp. 6-8).

This is not persuasive for the reason of record. Simmons et al teach a method of increasing resistance to a plant pathogen by transforming a plant with a recombinant expression cassette comprising a nucleic acid encoding a Bax inhibitor I protein having at least 85% sequence identity to SEQ ID NO: 2 under the control of a root-specific, fruit-specific, seed-specific or flower-specific promoters; Simmons et al teach various methods of transforming a plant cell, selecting transformed cells, and regenerating a stably transformed plant from the plant cell; plants to be transformed include monocots and dicots such as maize, soybean, tobacco, potato, tomato, sunflower, canola, wheat, rice, and barley; pathogens include fungal pathogens such as *Alternaria*, *Botrytis*, *Erysiphe*, *Rhizopus oryzae*, *Rhizopus*, *Puccinia helianthi*, *Verticillium*, *Erwinia*, *Cephalosporium*, *Phytophthora* and *Fusarium* (pages 44-46). The cited further teaches

that either heterologous or non-heterologous promoters can be used with BI1 nucleic acids in expression cassettes to drive expression of antisense nucleic acids to reduce, increase, or alter concentration of the BI1 proteins in a desired tissue. The transgenic plants expressing BI1 protein in the roots, flowers or seeds tissues are expected to possess unaltered BI1 activity/protein in leaf epidermis.

At pages 67-68, Simmons et al teach that disease symptoms usually result from cell death in infected tissues; it states for example, "*Fusarium moniliforme* growth in maize appears dependent on the presence of dead, senescing or decaying tissues. Among the dead or decaying tissues that are often so exploited by *Fusarium* are silks, husks, pericarp or cob.....However, this dependency of *Fusarium* upon dead tissue availability could be turned into an advantage for improving maize resistance to it, if death or senescence can be delayed." At Example 7, Simmons et al teach methods of altering BI1 expression in transgenic plants using tissue-specific promoters. In Example 11 , the cited reference teaches methods of inducing resistance against ear mold disease by altering expression of the BI1 gene using promoters specific to the tissue most accounting for ear mold ingress, namely silks, husks, pericarp or cob to retard cell death and senescence. Example 13 of the specification shows reducing the level maize BI1 in tapetum tissues using antisense BI1 constructs containing tapetum -specific promoter.

Therefore, one of ordinary skill in the art at the time this application was filed would be able to make a recombinant expression vector comprising any known BI1 gene such as the BI1 gene taught by Huchelhoven et al, with any desired tissue specific

promoter (the tissue most accounting for the pathogen to control) and use the recombinant vector to transform plants including monocot and dicot plants to produce transgenic plants having resistance to a pathogen as taught by Simmons et al. One would have been motivated to use a BI1 gene with a tissue-specific promoter, given that plant disease symptoms usually result from cell death and given that BI1 genes are known to inhibit cell death and as a result increase pathogen resistance as taught by Simmons et al. In addition, since the rejection is one of obviousness and not one of anticipation, none of the cited references need teach BI1 gene is unchanged or reduced in leaf epidermis or teach the use of a tuber or a mesophyll-specific promoter with the BI1 gene to transform a plant.

In *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art.” It states “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”*Id.* at \_\_\_, 82 USPQ2d at 1395. The Supreme Court further stated that:

“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at \_\_\_, 82 USPQ2d at 1396.

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at \_\_\_, 82 USPQ2d at 1396.

See also *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." Id. at \_\_\_, 82 USPQ2d at 1395"; *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007); and *Ex parte Smith*...USPQ2d-20 (Bd. Pat. App & Interf. June 25, 2007) (citing KRS, 82 USPQ2d at 1396)

#### Remarks

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Glazebrooke et al (WO 2003000906-A2, published 01/03/2003). Glazebrooke et al teach an isolated polynucleotide encoding a Bax1 protein having at least 89% sequence identity to SEQ ID NO: 2 (see attached alignment of sequences) and methods of its use in transgenic plants to induce resistance.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI  
12/6/2008

/Medina A Ibrahim/  
Primary Examiner, Art Unit 1638